

**REMARKS / ARGUMENTS**

This amendment is submitted in full response to the outstanding Office Action dated December 11, 2006 wherein claims 1-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Wyszogrodzki (U.S. Patent No. 6,248,120).

For the reasons set forth in greater detail hereinafter, the outstanding rejections are respectfully traversed.

**Issues Under 35 U.S.C. 102**

Before reviewing the substantive issues with regard to the rejection of the claims under 35 U.S.C. §102, the Applicant respectfully points out the well established requirement that:

For a prior art reference to anticipate in terms of 35 U.S.C. §102, **every** element of the claimed invention must be **identically** shown in a single reference. Diversitech Corp. v. Century Steps, Inc., 7 USPQ2d 1315, 1317 (Fed. Cir. 1988) (emphasis added).

Moreover, this burden on the U.S. Patent and Trademark Office ("PTO") is further compounded by the fact that the Federal Circuit has stated that within the single reference:

[t]he identical invention must be shown in as complete detail as is contained in the patent claim. Richardson v. Suzuki Motor Co. Ltd., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

And, more recently, the Federal Circuit has further expanded this principle to include that:

An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention. Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002).

As such, if an Applicant can establish that at least one claimed element is not present or is not identically disclosed in complete detail in the prior art reference put forth by the PTO, the grounds for rejection pursuant to 35 U.S.C. §102 of each claim comprising that element have been overcome. Furthermore, once the grounds for rejection under 35 U.S.C. §102 have been overcome, the PTO can not merely turn to 35 U.S.C. §103 as a basis for maintaining a rejection without first meeting the requisite burden.

Looking in detail to Wyszogrodzki, it discloses a device including a pair of projections 12 of the lancet that rest directly on the wings 11 of the sleeve 1. Moreover, the structure is such that the wings 11 are continuously under tension and pressure to break as a result of the linear force of the spring. Additionally, as the lancet of Wyszogrodzki is

pushed back into the housing, the spring becomes more and more compressed, thus continuously increasing the amount of breaking pressure and tension that is being exerted on those small wings. In particular, even though in the ideal operation of Wyszogrodzki it is not until the lancet abuts the back of the housing that the wings 11 break, because the Wyszogrodzki device does not have a release element that affirmatively pivots the wings out of engagement with the cocking seat, as in the Applicant's claimed invention, the wings 11 are necessarily intended to be broken merely by sufficient linear pressure being exerted on them. Accordingly, given such a structure that does not include a release element to pivot the projections 12, the Wyszogrodzki device is susceptible to premature firing as the spring itself is exerting considerable amounts of continuously increasing linear pressure. Furthermore, because the Wyszogrodzki device does not have the release element that pivotally disengages the engagement element from the cocking seat, the wings 11 can be susceptible to breaking at different points, such as if one wing is weaker than another, or can result in different lancet devices breaking at different points, thus possibly resulting in imprecise firing.

Conversely, in the Applicant's claimed device the engagement element is engaged by the cocking seat in a manner whereby the normal linear compression force associated with pushing the cocking seat into the housing does not result in disengagement and firing, but rather the separate release element disposed on the housing must affirmatively cause pivoting disengagement. Moreover, it is the disengagement by the release element, and not merely difficult to control added linear pressure, that results in the breaking of the single use pivot of the engagement element. As such, the Applicant's claimed invention can provide greater security, uniformity and control over when the lancet will fire, both as to each individual lancet and style of lancet.

Accordingly, it is urged that the patent to Wyszogrodzki does not disclose each and every element of the Applicant's claimed invention, and therefore, does not anticipate the Applicant's claimed invention. Furthermore, given that the structure of the Applicant's claimed device is very different and operates in a very different manner from that taught by Wyszogrodzki, a person of ordinary skill in the art would not have thought to alter the teachings of Wyszogrodzki, nor would they have been so motivated by Wyszogrodzki itself, in a

manner that approaches the structure of the Applicant's claimed invention.

Based on the above amendments and remarks reconsideration of this application is hereby requested. It is believed that this application is now in condition for allowance and such action is respectfully requested.

In addition, a request for an appropriate extension of time is enclosed herewith along with the corresponding PTO fee. In the event that any additional fee may be required by the filing of this paper, the Commissioner is hereby authorized to charge any fees and/or credits to our **Deposit Account No. 13-1227**.

Respectfully Submitted,

MALLOY & MALLOY, P.A.  
Attorneys for Applicant  
2800 S.W. 3<sup>rd</sup> Avenue  
Historic Coral Way  
Miami, Florida 33129  
(305) 858-8000

By: 

Peter A. Matos  
Reg. No. 37,884

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